

WHO Emergency Use Assessment Coronavirus disease (COVID-19) IVDs PUBLIC REPORT

**Product: Diagnostic Kit for Novel-Coronavirus (2019-nCoV) RNA
(Isothermal Amplification- Real Time Fluorescence Assay)**

EUL Number: EUL 0522-208-00

Outcome: Not Accepted.

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:

- Quality Management Systems Review and Plan for Post-Market Surveillance: desk-top review of the manufacturer's Quality Management System documentation and specific manufacturing documents;
- Product Dossier Review: assessment of the documentary evidence of safety and performance.

Diagnostic Kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification- Real Time Fluorescence Assay) with product code U20223, manufactured by UStar Biotechnologies (Hangzhou) Ltd., Bldg C, Fl 1-2 and Bldg A, Fl 5 399 Qiuyi Rd., Changhe Street, Beijing District Hangzhou 310052, China, is not eligible for WHO procurement.

Quality Management Systems Review

To establish the eligibility for WHO procurement, UStar Biotechnologies (Hangzhou) Ltd was asked to provide up-to-date information about the status of their quality management system.

Upon review of the submitted documentation by UStar Biotechnologies (Hangzhou) Ltd in support of a desk assessment on the Quality Management System of the manufacturer, the information submitted did not constitute adequate evidence of compliance with ISO 13485: 2016 Medical devices - Quality management systems - Requirements for regulatory purposes and the requirements described in the *"Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid, PQDx_ 347"*.